

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CYTIVA SWEDEN AB, and
GLOBAL LIFE SCIENCES
SOLUTIONS USA, LLC,

Plaintiffs,

V.

BIO-RAD LABORATORIES, INC.,

Defendant.

[REDACTED]

Redacted: Public Version

C.A. No. 18-1899-CFC-SRF

CONSOLIDATED

**PLAINTIFFS' CONCISE STATEMENT OF FACTS IN SUPPORT OF
THEIR OPENING BRIEF IN SUPPORT OF ITS MOTION FOR
SUMMARY JUDGMENT OF INFRINGEMENT OF
CLAIM 1 OF U.S. PATENT NO. 9,671,420,
CLAIM 1 OF U.S. PATENT NO. 9,709,589,
CLAIM 14 OF U.S. PATENT NO. 9,709,591, AND
CLAIM 16 OF U.S. PATENT NO. RE47,124**

OF COUNSEL:

Matthew M. Wolf

Jennifer Sklenar*

Amy DeWitt

Bridgette C. Boyd

ARNOLD & PORTER KAYE

SCHOLER LLP

601 Massachusetts Avenue, NW

Washington D.C. 20001

(202) 942-5462

John W. Shaw (No. 3362)

Nathan R. Hoeschen (No. 6232)

SHAW KELLER LLP

I.M. Pei Building

1105 North Market Street, 12th Floor


Wilmington, DE 19801

(302) 298-0700

jshaw@shawkeller.com

nhoeschen@shawkeller.com

Attorneys for Plaintiffs



Jeffrey A. Miller
Joseph B. Palmieri
ARNOLD & PORTER KAYE
SCHOLER LLP
3000 El Camino Real
Building 5, Suite 500
Palo Alto, CA 94306
(650) 319-4500

Ryan M. Nishimoto
ARNOLD & PORTER KAYE
SCHOLER LLP
777 South Figueroa Street, 44th Floor
Los Angeles, CA 90017
(213) 243-4000

Michael J. Sebba
ARNOLD & PORTER KAYE
SCHOLER LLP
250 West 55th Street
New York, NY 10019
(212) 836-8000

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CONCISE STATEMENT OF FACTS

1. Bio-Rad's NGC system is made up of four main models: Quest, Scout, Discover and Discover Pro. These models have the same architecture and can have the same modules installed therein. The differences between models relate to the modules that are included as standard equipment, whether they include an expansion housing and if so, how many. Ex. 5, p. 87-88; Declaration of Dr. Steven Wereley ("Wereley") Wereley, ¶¶54-59

2. The NGC's Instrument Guide states that it is a liquid chromatography system, and that the system "rapidly automates" the purification of biomolecules. Wereley, ¶¶60-61; Ex. 5, p. 11; Ex. 6 (BRGE00065119); Ex. 7 (Mavandadi Tr.) 106:5-15.

3. Automated liquid chromatography systems have certain components for performing liquid chromatography, including an injection valve, a pump, an inline detector that can measure the relevant characteristics of the liquid exiting the chromatography column, and control software for processing, displaying, and/or storing the results, which operate without manual intervention. Wereley, ¶63.

4. All models of Bio-Rad's NGC come standard with a sample inject valve module (Wereley, ¶88; (Ex. 5, pp. 37, 87); Ex. 8 (Gale Tr.) 355:13-16), two system pump modules (Wereley, ¶87; Ex. 5, pp. 28, 87), a UV monitor module that

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measures characteristics of the liquid exiting the chromatography column (Wereley, ¶172; Ex. 5, pp. 65-72, 87; Ex. 8 (Gale Tr.) 357:2-359:2)) and control software for automatically controlling the liquid chromatography system (Ex. 8 (Gale Tr.) 356:3-7; Ex. 3 (Chapman Tr.) 333:18-334:2; Ex. 9, p. 21). *See also* Wereley, ¶¶60-64, 73-82.

5. Each NGC model has a housing. Wereley, ¶¶65-72; Ex. 10 (Bland Tr.) 86:2-86:17; Ex. 11 (BRGEDEL445194); Ex. 3 (Chapman Tr.) 541:6-541:22.

6. Each NGC model has a single board computer that controls the system. Ex. 10 (Bland Tr.) 36:1-36:13.

7. The single board computer is installed inside the housing. Wereley, ¶78; Ex. 10 (Bland Tr.) 37:8-38:18).

8. Each module communicates with the single board computer via a bus. Wereley, ¶79-80; Ex. 10 (Bland Tr.) 144:1-144:11; Ex. 13 (BRGE96083); Ex. 14 (BRGEDEL450748).

9. All NGC models come with two system pump modules, a sample inject module, and a UV detector module. Wereley, ¶¶85-88; Ex. 5, p. 87.

10. Each of these modules can be inserted into and removed from positions in the housing. Wereley, ¶¶89-90; Ex. 5, p. 19; Ex. 12 (BRGEDEL401642, BRGEDEL401629).

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11. Each module has a standardized size and shape that allows it to be exchanged with another component. Wereley, ¶¶89; Ex. 5, pp. 237-238; Ex. 10 (Bland Tr.) 98:13-101:1.

12. All NGC models have modules that contain a section that includes fluidics components and does not include non-fluidics components. Wereley, ¶¶97-106; Ex. 13 (BRGE96090); Ex. 14 (BRGEDEL450753); Ex. 3 (Chapman Tr. 529:12-530:17, 528:16-529:10); Ex. 5, pp. 29, 37-38, 40; Ex. 15 (Gale Rebuttal Report) (Bio-Rad's expert does not refute that the fluidics components identified by Dr. Wereley do not contain non-fluidics components).

13. All NGC models have modules that contain a section that includes electrical components and does not include fluidics component. Wereley, ¶¶110-115; Ex. 13 (BRGE0096090), Ex. 14 (BRGEDEL000450753)); Ex. 3 (Chapman Tr.) 529:12-530:17, 528:16-529:10; Ex. 16 (BRGEDEL317444, BRGEDEL317453-317455, BRGEDEL317564); Ex. 15 (Gale Rebuttal Report) ¶¶117, 122-123 (BioRad's expert does not take issue with whether the non-fluidic section, as identified by Dr. Wereley, contains fluidic components).

14. All NGC models have a bus connector for directly connecting the interchangeable modular component with the system bus. Wereley, ¶¶117-127.

15. All NGC models have a panel member that separates an internal non-fluidics section from an external fluidics section. Wereley, ¶¶129-131; Ex. 5, pp. 28,

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37; Ex. 10 (Bland Tr.) 151:4-155:21); Ex. 3 (Chapman Tr.) 388:18-21; Ex. 15 (Gale Rebuttal Report) ¶78 (Bio-Rad's expert does not refute that the structure Dr. Wereley identifies as the claimed panel member separates the non-fluidics section and fluidics section, as they are identified by Dr. Wereley).

16. All NGC models have a housing comprising a liquid handling panel with at least four component receiving positions arranged in a two dimensional array and adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing. Wereley, ¶¶138-140; Ex. 5, p. 22, 237-238.

17. All NGC models have component receiving position that includes a complementary connector for connecting the bus connector of the interchangeable modular component inserted therein to said system bus. The NGC has a "backplane" that the back of each module abuts upon insertion into the housing and the backplane contains a series of connectors that mate with the connector on the back of an inserted module. Wereley, ¶¶144-146; Ex. 10 (Bland Tr.) 144:1-11.

18. Each NGC module has a CPU. Wereley, ¶¶150-155; Ex. 13 (BRGE96081), Ex. 14 (BRGEDEL450746); Ex. 10 (Bland Tr.) 105:2-105:17; Ex. 17 (BRGEDEL98274); Ex. 18 (GEHCDEL129737, at GEHCDEL129796).

19. The CPU on each module allows the interchangeable modular component to independently perform operations in response to instructions over the

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system bus. Wereley, ¶¶79-80, 157-159; Ex. 2 (Iovanni Tr.) 105:9-105:22; Ex. 10 (Bland Tr.) 107:13-108:13, 144:1-144:11; Ex. 13 (BRGE96083); Ex. 14 (BRGEDEL450748).

20. Each module receives instructions over the bus from the master control unit. Decl. of Nenad Vukicevic (“Vukicevic”), ¶¶5-9; Ex. 10 (Bland Tr.) 106:20-107:1, 105:18-108:13.

21. Each NGC model has a master control unit that is arranged to automatically identify interchangeable modular components. Wereley, ¶164; Ex. 5, p. 19; Ex. 12 (BRGEDEL401629); Ex. 10 (Bland Depo. Tr.) 81:19-85:22; Vukicevic, ¶10.

22. Each NGC model can accommodate any module, regardless of whether a module comes standard with a particular system. Wereley, ¶¶169-170; Ex. 5, p 87-88.

23. The NGC Quest comes standard with a sample inject valve module and a customer can purchase additional valve modules and install them into the system, *e.g.*, a pH valve module. Wereley, ¶¶169-170; Ex. 5, p 87-88.

24. Each NGC model comes standard with a UV detector module. Wereley, ¶¶169-170, Ex. 5, p 87-88.

25. The housing unit of each NGC model has a plurality of receiving portions. Wereley, ¶¶221-223; Ex. 5, pp. 90-91, 237-238.

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26. Each of Bio-Rad's UV monitor modules have a fluid handling section. Wereley, ¶¶226, 234-235; Ex. 19 (BRGEDEL282560), Ex. 20 (BRGEDEL281538); Ex. 3 (Chapman Tr.) 532:4-534:17; Ex. 5, p. 66-67, 69, 205.

27. Each of the two system pump modules, sample inject valve module, and UV detector modules is configured for insertion into the receiving positions of the housing unit. Wereley, ¶215; Ex. 5 p. 19; Ex. 12 (BRGEDEL401629, BRGEDEL401642); Ex. 10 (Bland Tr.) 98:13-101:1.

28. Each NGC model has modules that are readily interchangeable amongst similarly sized and shaped receiving positions of the housing unit, such that positioning of the modular fluid handling unit with respect to other modular fluid handling units permits a fluid flow path to be readily modified, wherein the fluid flow path is formed by fluidic connections between the modular fluid handling units. Wereley, ¶¶243-250; Ex. 5, pp. 19, 233-239; Ex. 21 (BRGEDEL293539, BRGEDEL293542); Ex. 22, pp. 2-3; Ex. 10 (Bland Tr.) 100:8-101:1.

29. The only difference between claim 1 of the '591 patent and claim 1 of the '420 patent is that the former requires only two fluid handling units arranged as interchangeable module components and they need not be arranged in a two dimensional array. Wereley, ¶¶264-265.

30. The two system pump modules that come with each NGC model have fluid connectors for connecting the fluid handling unit to a liquid chromatography

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fluid path and the connectors are on the external side of the panel member. Wereley, ¶286, Ex. 23 (BRGEDEL1507).

31. When interconnecting the fluid inputs and outputs on the NGC, fluid will pass through the system. Wereley, ¶¶295-296; Ex. 5, p. 22; Ex. 21, (BRGEDEL293539).

32. The panel member for each of the NGC modules enables mounting of the module to the housing. Wereley, ¶305; Ex. 5, p. 235; Ex. 10 (Bland Tr.) 151:4-155:21; Ex. 3 (Chapman Tr.) 387:10-17.

Respectfully submitted,

/s/ John W. Shaw

John W. Shaw (No. 3362)
Nathan R. Hoeschen (No. 6232)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
nhoeschen@shawkeller.com
Attorneys for Plaintiffs

OF COUNSEL:
Matthew M. Wolf
Jennifer Sklenar*
Amy DeWitt
Bridgette C. Boyd
ARNOLD & PORTER KAYE
SCHOLER LLP
601 Massachusetts Avenue, NW
Washington D.C. 20001
(202) 942-5462

Jeffrey A. Miller
Joseph B. Palmieri
ARNOLD & PORTER KAYE
SCHOLER LLP
3000 El Camino Real
Building 5, Suite 500
Palo Alto, CA 94306
(650) 319-4500

[REDACTED]

Ryan M. Nishimoto
ARNOLD & PORTER KAYE
SCHOLER LLP
777 South Figueroa Street, 44th Floor
Los Angeles, CA 90017
(213) 243-4000

Michael J. Sebba
ARNOLD & PORTER KAYE
SCHOLER LLP
250 West 55th Street
New York, NY 10019
(212) 836-8000

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Dated: December 15, 2020

CERTIFICATE OF COMPLIANCE

Pursuant to the Court's November 6, 2019 Standing Order, I hereby confirm that this brief complies with the type and number limitations set forth in the Standing Order. I certify that this document contains 1,304 words, which were counted using the word count feature in Microsoft Word, in 14-point Times New Roman font.

/s/ John W. Shaw _____

John W. Shaw (No. 3362)

Nathan R. Hoeschen (No. 6232)

SHAW KELLER LLP

I.M. Pei Building

1105 North Market Street, 12th Floor

Wilmington, DE 19801

(302) 298-0700

jshaw@shawkeller.com

nhoeschen@shawkeller.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I, John W. Shaw, hereby certify that on December 15, 2020, this document was served on the persons listed below in the manner indicated:

BY EMAIL

David E. Moore
Bindu A. Palapura
Stephanie E. O'Byrne
Alan R. Silverstein
POTTER ANDERSON
& CORROON LLP
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
(302) 984-6000
dmoore@potteranderson.com
bpalapura@potteranderson.com
sobyne@potteranderson.com
asilverstein@potteranderson.com

Anne S. Toker
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
51 Madison Ave, 22nd Floor
New York, NY 10010
(212) 849-7000
annetoker@quinnemanuel.com

David Bilsker
Andrew E. Naravage
Felipe Corredor
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
50 California Street, 22nd Floor
San Francisco, CA 94111
(415) 875-6600
davidbilsker@quinnemanuel.com
andrewnaravage@quinnemanueal.com
felipecorredor@quinnemanuel.com

Kevin P.B. Johnson
Brian C. Cannon
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
555 Twin Dolphin Dr., 5th Floor
Redwood Shores, CA 94065
(650) 801-5015
kevinjohnson@quinnemanuel.com
briancannon@quinnemanuel.com

Sean D. Damon
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
1300 I Street NW Suite 900
Washington, D.C. 20005
(202) 538-8260
seandamon@quinnemanuel.com

/s/ John W. Shaw

John W. Shaw (No. 3362)

Nathan R. Hoeschen (No. 6232)

SHAW KELLER LLP

I.M. Pei Building

1105 North Market Street, 12th Floor

Wilmington, DE 19801

(302) 298-0700

jshaw@shawkeller.com

nhoeschen@shawkeller.com

Attorneys for Plaintiffs